UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

MARGARET NYGREN, Surviving Spouse and Executor of the Estate of EDWARD NYGREN, Deceased,	Civil Action No.
Plaintiff,	07 CV 7271
v.	**COMPLAINT**
NOVARTIS PHARMACEUTICALS CORPORATION, PROCTER & GAMBLE PHARMACEUTICALS, INC. and AVENTIS PHARMACEUTICALS, INC.,	**JURY TRIAL DEMANDED**
Defendants.	

Plaintiff Margaret Nygren ("Plaintiff"), surviving spouse and Executor of the estate of Edward Nygren, deceased, by her attorneys, for her Complaint against defendants Novartis Pharmaceuticals Corporation ("Novartis"), Procter & Gamble Pharmaceuticals, Inc. ("P&GP") and Aventis Pharmaceuticals, Inc. ("Aventis") (also, collectively, "defendants"), alleges:

1. This is a civil action for damages suffered by Edward Nygren as a result of his being prescribed and injected with

Novartis' drug Zometa and being prescribed and taking P&GP and Aventis' drug Actonel.

PARTIES

2. Plaintiff Margaret Nygren is a citizen and resident of the State of Pennsylvania, residing in Edwardsville, Pennsylvania.

3. Edward Nygren, prior to his death on November 4, 2006, was a citizen and resident of the State of Pennsylvania, residing in Edwardsville, Pennsylvania.

4. At all times herein mentioned, Novartis was and is a Delaware corporation, with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936-1080.

5. At all times herein mentioned, P&GP was and is a Ohio corporation, with its principal place of business at One Procter Gamble Plaza, Cincinnati, Ohio 45202-3393.

6. At all times herein mentioned, Aventis was and is a Delaware corporation, with its principal place of business at 200 Crossing Boulevard, Bridgewater, New Jersey 08807.

7. At all times herein mentioned, Defendants did business in the States of New York and Pennsylvania.

JURISDICTION

8. This Court has original jurisdiction over this action under 28 U.S.C. § 1332, in that the amount in controversy exceeds seventy five thousand dollars ($75,000.00), Plaintiff is a citizen of a State which is different from the States where defendants are incorporated and have their principal places of business, and Edward Nygren was a citizen of a State which is different from the States where defendants are incorporated and have their principal places of business.

FACTUAL BACKGROUND

9. Novartis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Zometa.

10. Zometa is the brand name of zolodrenic acid, which is in a class of prescription drugs called bisphosphonates. Zometa is administered intravenously and/or by injection.

11. Zometa was approved by the United States Food and Drug Administration for treatment of hypercalcemia and bone matastases.

12. The product literature prepared by Novartis and circulated to physicians for use in prescribing the drug contained no warning about osteonecrosis of the jaw or other bone structure.

13. In 2002 or before, Novartis received information from a physician that several of the physician's patients who were given Aredia, another bisphosphonate designed and manufactured by Novartis, were diagnosed with osteonecrosis of the jaw and that he believed a causal relationship existed between the use of Aredia and osteonecrosis of the jaw.

14. Another group of physicians published a report about patients being diagnosed with osteonecrosis of the jaw after being given Aredia and Zometa. The report said, "the jaw complications presented in this review have had a major negative effect on the quality of daily life for each of these patients" and determined that "bisphosphonates may be at least partially responsible." Ruggiero, et al., "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004).

15. Novartis sent warnings to physicians regarding the risk of osteonecrosis of the jaw with the use of Aredia and Zometa in September 2004 and May 2005.

16. Edward Nygren was prescribed and given Zometa.

17. As a result of being given and/or injected with Zometa, Edward Nygren developed osteonecrosis of the jaw.

18. As a result of being given and/or injected with Zometa Edward Nygren suffered compensable injuries, including but not limited to the following:

a. severe and permanent physical and medical injuries and associated disabilities;

b. severe pain and suffering;

c. severe mental anguish;

d. loss of enjoyment of life;

e. increased risk of health problems;

f. medical care and monitoring; and

g. loss of income.

19. P&GP and Aventis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel.

20. Actonel is the brand name of risedronate sodium, which is in a class of prescription drugs called bisphosphonates. Actonel is taken orally.

21. Actonel was approved by the United States Food and Drug Administration for treatment of osteoporosis.

22. The product literature prepared by P&GP and Aventis and circulated to physicians for use in prescribing the drug contained no warning about osteonecrosis of the jaw or other bone structure.

23. In 2002 or before, P&GP and Aventis knew or should have known that a physician reported that several of his patients who were given Aredia, another bisphosphonate, were diagnosed with osteonecrosis of the jaw and that the physician believed a causal relationship existed between the use of bisphosphonates and osteonecrosis of the jaw.

24. P&GP and Aventis never issued any warnings or changed their product literature to warn of the risk of osteonecrosis of the jaw.

25. Edward Nygren was prescribed and took Actonel.

26. As a result of taking Actonel, Edward Nygren developed osteonecrosis of the jaw.

27. As a result of taking Actonel Edward Nygren suffered compensable injuries, including but not limited to the following:

a. severe and permanent physical and medical injuries and associated disabilities;

b. severe pain and suffering;

c. severe mental anguish;

d. loss of enjoyment of life;

e. increased risk of health problems;

f. medical care and monitoring; and

g. loss of income.

FIRST CLAIM FOR RELIEF

[Strict Product Liability - Design Defect]

28. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 27 of the Complaint as if they were set forth here in full.

29. Novartis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Zometa.

30. Zometa as designed, manufactured and sold by Novartis was defective in design or formulation in that it was unreasonably dangerous.

31. Zometa as designed, manufactured and sold by Novartis was defective in design or formulation in that its foreseeable risks exceeded the benefits associated with the design or formulation.

32. Zometa as designed, manufactured and sold by Novartis was defective due to inadequate warnings because Novartis knew or should have known that the product created a risk of harm to consumers.

33. Zometa as designed, manufactured and sold by Novartis was defective due to inadequate testing.

34. As the proximate cause and result of the defective condition of Zometa as designed, manufactured and sold by Novartis, Edward Nygren was injured.

35. P&GP and Aventis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel.

36. Actonel as designed, manufactured and sold by P&GP and Aventis was defective in design or formulation in that it was unreasonably dangerous.

37. Actonel as designed, manufactured and sold by P&GP and Aventis was defective in design or formulation in that its foreseeable risks exceeded the benefits associated with the design or formulation.

38. Actonel as designed, manufactured and sold by P&GP and Aventis was defective due to inadequate warnings because P&GP and Aventis knew or should have known that the product created a risk of harm to consumers.

39. Actonel as designed, manufactured and sold by P&GP and Aventis was defective due to inadequate testing.

40. As the proximate cause and result of the defective condition of Actonel as designed, manufactured and sold by P&GP and Aventis, Edward Nygren was injured.

SECOND CLAIM FOR RELIEF

[Strict Product Liability - Failure To Warn]

41. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 27 of the Complaint as if they were set forth here in full.

42. Novartis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Zometa.

43. Zometa as designed, manufactured and sold by Novartis was not accompanied by proper warnings regarding possible adverse side effects.

44. Novartis knew or should have known about the possible adverse side effects of Zometa, including osteonecrosis of the jaw.

45. As the proximate cause and result of Novartis' failure to properly warn physicians and consumers, Edward Nygren was injured.

46. P&GP and Aventis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel.

47. Actonel as designed, manufactured and sold by P&GP and Aventis was not accompanied by proper warnings regarding possible adverse side effects.

48. P&GP and Aventis knew or should have known about the possible adverse side effects of Actonel, including osteonecrosis of the jaw.

49. As the proximate cause and result of P&GP and Aventis' failure to properly warn physicians and consumers, Edward Nygren was injured.

THIRD CLAIM FOR RELIEF

[Negligence]

50. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 27 of the Complaint as if they were set forth here in full.

51. Novartis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Zometa.

52. Novartis had a duty to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Zometa, including a duty to assure that users, like Edward Nygren, did not suffer unreasonable adverse side effects, such as osteonecrosis of the jaw.

53. Novartis failed to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Zometa in that Novartis knew or should

have known that Zometa created an unreasonable risk of osteonecrosis of the jaw.

54. Novartis was negligent in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Zometa.

55. As the proximate cause and result of Novartis' negligence, Edward Nygren was injured.

56. P&GP and Aventis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel.

57. P&GP and Aventis had a duty to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Actonel, including a duty to assure that users, like Edward Nygren, did not suffer unreasonable adverse side effects, such as osteonecrosis of the jaw.

58. P&GP and Aventis failed to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Actonel in that P&GP and Aventis knew or should have known that Actonel created an unreasonable risk of osteonecrosis of the jaw.

59. P&GP and Aventis were negligent in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Actonel.

60. As the proximate cause and result of P&GP and Aventis' negligence, Edward Nygren was injured.

FOURTH CLAIM FOR RELIEF

[Breach of Express Warranty]

61. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 27 of the Complaint as if they were set forth here in full.

62. Novartis expressly warranted, by and through statements made by Novartis or its authorized agents, that Zometa was safe, effective, and fit for its intended use.

63. Edward Nygren, and his agents, relied on the skill, judgment and representations of Novartis.

64. Zometa did not conform to Novartis' express warranties in that it was not safe and fit for its intended use because it caused serious adverse side effects, including osteonecrosis of the jaw.

65. As the proximate cause and result of Novartis' breach of its express warranties, Edward Nygren was injured.

66. P&GP and Aventis expressly warranted, by and through statements made by P&GP and Aventis or their authorized agents, that Actonel was safe, effective, and fit for its intended use.

67. Edward Nygren, and his agents, relied on the skill, judgment and representations of P&GP and Aventis.

68. Actonel did not conform to P&GP Aventis' express warranties in that it was not safe and fit for its intended use because it caused serious adverse side effects, including osteonecrosis of the jaw.

69. As the proximate cause and result of P&GP and Aventis' breach of their express warranties, Edward Nygren was injured.

FIFTH CLAIM FOR RELIEF

[Breach of Implied Warranty]

70. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 27 of the Complaint as if they were set forth here in full.

71. Novartis impliedly warranted to Edward Nygren, and his agents, that Zometa was of merchantable quality and was safe and fit for its intended use.

72. Edward Nygren, and his agents, relied on Novartis' skill and judgment.

73. Zometa was not of merchantable quality or safe and fit for its intended use in that it caused serious adverse side effects, including osteonecrosis of the jaw.

74. As the proximate cause and result of Novartis' breach of its implied warranties, Edward Nygren was injured.

75. P&GP and Aventis impliedly warranted to Edward Nygren, and his agents, that Actonel was of merchantable quality and was safe and fit for its intended use.

76. Edward Nygren, and his agents, relied on P&GP and Aventis' skill and judgment.

77. Actonel was not of merchantable quality or safe and fit for its intended use in that it caused serious adverse side effects, including osteonecrosis of the jaw.

78. As the proximate cause and result of P&GP and Aventis' breach of its implied warranties, Edward Nygren was injured.

PRAYER FOR RELIEF

WHEREFORE, plaintiff Margaret Nygren, surviving spouse and Executor of the estate of Edward Nygren, deceased, rspectfully prays for relief and judgment against the defendants as follows:

(a) compensatory damages in an amount to be determined at trial;

(b) attorneys' fees, expenses, and costs of this action; and

(c) for any other relief this Court deems just and proper under the circumstances.

JURY TRIAL DEMAND

Plaintiff respectfully requests a trial by jury on all triable issues pursuant to Rule 38 of the Federal Rules of Civil Procedure.

Dated: New York, New York
August 14, 2007

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